

REMARKS

Examiner Swiger is thanked for withdrawing the previous rejections in light of previous remarks. However, in the pending Office Action he has again rejected the pending claims over one or more references. After reviewing the newly-cited references, it is noted that they do not anticipate or render obvious the pending claims. Accordingly, reconsideration of the present claims and withdrawal of the pending rejections is respectfully requested.

The Claims Are Not Anticipated by the Casey Reference

Claims 1-6, 10-16 and 38-39 were rejected as allegedly anticipated by U.S. Patent No. 4,781,183 to Casey. The Casey reference does not include all features in any of those claims, and therefore this rejection should be withdrawn.

The Casey reference is principally drawn to particular compositions that can be made into surgical structural elements. The compositions are either mixtures of polymer and "particulate filler" (col. 5, ll. 51-61), or fibers mixed or impregnated with polymer (col. 5, l. 63-col. 6, l. 19). In each case, a homogeneous (through mixing or impregnation) material is created. As the Summary in Casey makes clear, what is disclosed is a bioabsorbable device that has an adjustable initial modulus and that loses "properties" at a "controllable, predictable rate." See col., 3, ll. 54-65. The device is made of a material that "consist[s] of" a bioabsorbable polymer and a "reinforcement fiber," which are combined to make a uniform material. See col. 3, l. 66-col. 4, l. 10. Casey teaches using such a material in making what appears to be a plate with holes through which screws can be inserted to attach the device to a bone.

Independent claim 1 recites, among other things, an elongate member for engagement to multiple bone portions and that allows translational or rotational movement of one such portion

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relative to another. There is no disclosure in Casey that its device 1 (shown in its Figures 4-7) allows translational or rotational movement of bone portions. Column 6, lines 20-42 of Casey is the only text concerning that device 1, and all that is stated concerning attachment is that the device is attached mechanically or by bonding. The example of screw attachment shown in Figure 7 show screws firmly seated in device 1, so that the device cannot move with respect to each portion of bone 4, and thus the portions cannot move with respect to each other. The bonding example suggested in the text also results in the device 1 both bone portions all fixed together. Device 1 is designed to "allow the best possible chance for uniform healing of the fracture," suggesting that it immobilizes the bone pieces until uniform healing occurs. Once the fracture is healed, the bone pieces do not move with respect to each other.

Thus, the disclosure of Casey is of a device 1 that does not allow movement of bone pieces on fixation. Once the bone is healed, no movement of the former bone pieces is possible. The information available from the Casey reference does not show or suggest any respective movement of bone pieces.

It is axiomatic that anticipation requires not only that all elements of the claim be present in a single reference, but that those elements "must be arranged as required by the claim." MPEP 2131 (citing *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)). The Office Action alleged that Casey's device 1 is an "elongate member" as in claim 1, and that the "reinforcement fiber" recited at the end of column 3 and the beginning of column 4 of Casey constitutes a "reinforcing component" as in claim 1. However, as already discussed Casey discloses a homogeneous material of polymer and "reinforcement fiber" out of which its device 1 is made. The claim recites an elongate member and a reinforcing component that is engaged to the elongate member. The "reinforcement fiber" of Casey is mixed or impregnated with polymer in order to

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create device 1 later. It is not engaged to an existing device 1. Assuming for argument's sake that mixing or impregnating with polymer is an "engaging," then Casey's "reinforcement fiber" is only engaged to polymer, not an "elongate member" as recited in claim 1.

Claims 2-6, 10-16 and 38-39 include all features of independent claim 1, and are also not anticipated by Casey for the reasons given above and/or on their own merit. For example, with regard to claim 10, Casey does not discuss loss of mass over particular times. In addition to lacking the subject matter of claim 10, its disclosure of use in uniform healing of long bone fractures (which generally heal in significantly less than one year) appears to teach away from retaining mass as recited in claim 10. With regard to claim 11, the Office Action does not identify which recited material(s) are disclosed in Casey, which appears limited to polyethylenes, poly(p-phenylene terephthalamide), and alumina. As to claim 14, Casey's "reinforcement fiber" is in the material used to make device 1, and device 1 has several holes. It is not possible for that "reinforcement fiber" to be within voids, as recited in claim 14, since the holes in Casey's device 1 are absences of the material of which the device 1 is made. The Office Action alleged that device 1 "may have a reinforcing component that may be placed in the plurality of voids" (emphasis added). The suggestion that Casey could or might have some element that could be used in a certain fashion does not state a sufficient case of anticipation, and in any event Casey does not disclose any "reinforcement fiber" in the holes of its device 1. As to claim 16, as already discussed device 1 is made of a material that consists of Casey's "reinforcement fiber" that is mixed with or impregnated with polymer. There is no disclosure in Casey of a "reinforcement fiber" that encases part of device 1.

As to claim 38, the Office Action does not provide an analysis of the "means" language used. Respectfully, it must be determined whether that language invokes Section 112, paragraph

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6, and if so, the appropriate limitation is to be considered the corresponding structures, materials or acts in the specification and equivalents thereof. MPEP 2181 (citing *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994)). Without those considerations, a case of anticipation of claim 38 cannot be made. Moreover, as noted above there is nothing in Casey's device 1 that allows movement of bone portions relative to each other.

The Claims Are Not Obvious over the Casey and Cohen References

Claims 17-21 were rejected as allegedly obvious over the Casey reference and the previously-cited U.S. Patent No. 6,206,882 to Cohen. Each of these claims is dependent from independent claim 1, and so all of the features of these claims are not shown in the combination of these references.

The combination of Casey and Cohen also do not show a portion configured to resist deformation as recited in claim 18. The Office Action did not identify such a portion, and Cohen's plate is designed to deform throughout its length by virtue of the slots placed along the whole length. As discussed above, Casey does not and cannot show its "reinforcing fiber" in a void in its device 1, and Cohen does not fill that lack. The references thus do not show the features recited in claim 21.

The Casey and Cohen references also teach away from the combination proposed in the Office Action. Casey's device 1 is designed for uniform fracture healing, which needs the immobilization of a rigid device. Cohen, on the other hand, teaches a plate that is designed to be flexible so as to provide some stabilization to vertebrae while allowing easy attachment and accommodate the curved configuration of the spinal column. Some flexing of the plate as the spinal column is moved is also apparently available. Further, Casey teaches the value of

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consistency and uniformity in the material used for device 1 and its characteristics, while Cohen teaches non-uniformity in the form of slots to enable use of its plate. Since Casey directs one of ordinary skill toward immobility and constancy, and Cohen directs toward adaptability, flexion and variation, they do not suggest a reasonable chance of success in the combination.

The Claims Are Not Obvious over the Casey and Severns References

Claims 24-32, 35, 47-52 and 57-62 were rejected as allegedly obvious over the Casey reference and U.S. Publication No. 2002/0173792 to Severns. Each of claims 24-32 and 35 is dependent from independent claim 1, and so all of the features of these claims are not shown in the combination of these references.

The combination of Casey and Severns also do not show an orthopedic rod as recited in claim 24. While the Office Action refers to Figure 1 of Severns as an orthopedic rod, the reference states that item 20 in Figure 1 is an intramedullary nail (paragraph 0040), which is placed within the medullary canal of a long bone (paragraph 0003). Severns also indicates that it concerns bone plates (paragraph 0002), but does not describe or refer to a rod at all. Severns also does not disclose any use with the spine, and so the spinal rod of claim 25 is not shown in the combination.

Severns does not show any reinforcing material that encases a portion of an orthopedic rod, as recited in claim 29. The Office Action alleged that items 46 of Severns were "reinforcing material." However, in addition to the fact that no orthopedic rod is shown, the items 46 of Severns do not encase any part of the intramedullary nail. Rather, each is a sleeve for a fastener, and that fastener is not an orthopedic rod. Severns also does not show a portion of an orthopedic rod configured to allow the rod to be deformed, as recited in claim 30. An intramedullary nail as

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in Severns is inserted into a medullary canal to assist healing of a long bone, and thus deformation of it is undesirable. Severns does not disclose any deformable portion of its nail.

Independent claim 47 includes features of claim 1 and other claims discussed above that are not disclosed in Casey or Severns. The remarks given above, including those relative to the recited elongate member and reinforcing component and their relationship, as well as those concerning the absence of an orthopedic rod, are equally applicable with respect to claim 47.

Claims 48-52 and 57-62 depend from claim 47, and are allowable on that basis and/or on their own merit. For example, claim 50 recites that the elongate member allows restricted movement of bone portions after a reinforcing component biodegrades. As discussed above with respect to claim 1, Casey's device 1 provides for uniform healing. No movement of the bone portions is possible when device 1 is placed so that uniform healing can occur, and once the healing has occurred no further movement of the parts of the healed bone is possible. Similarly, Severns' intramedullary nail holds bone parts fast with respect to each other on implantation, and when the long bone has healed, there is no possibility of its parts moving with respect to each other. The remarks given above with respect to claims 11, 25, and 29 apply equally to claims 57, 58, and 60, respectively. Method claim 62 includes all features of claim 47, and is not obvious for at least the reasons given above.

The Claims Are Not Obvious over the Casey, Cohen and Severns References

Claims 7-10, 22-23, 36-37 and 53-56 were rejected as allegedly obvious over the combination of all of the Casey, Cohen and Severns references. Each of these claims is dependent from either claim 1 or claim 47, and so the combination does not show all features of any of these claims.

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Respectfully, the Office Action does not establish that “general conditions of a claim are disclosed” in the cited references. The rejection of claims 7-10, 22-23, 36-37 and 53-56 depend on that unproved premise, and thus should be withdrawn.

Moreover, the references do not show or suggest even “general conditions” of the biodegradation characteristics in these claims. The Cohen reference does not disclose biodegradability at all. Casey discloses a biodegradable polymer mixed with or impregnated in a “reinforcement fiber” that may or may not be biodegradable. If the “fiber” is biodegradable, then Casey cannot suggest claim 7, since degradation will occur with respect to all of Casey’s device and none of an “elongate member” will remain engaged to bone. If the “fiber” is not biodegradable, then it does not suggest claim 7, which recites (through claim 1) a biodegradable reinforcing component. It was noted above that Casey does not discuss loss of mass of its device over particular times (as recited in claims 8, 10, 22-23, and 36-37). Its disclosure of use in uniform healing of long bone fractures (which generally heal in significantly less than one year) appears to teach away from retaining mass as recited in claims 10, 23 and 37. As to claim 9, Casey’s uniform healing means that once the healing has occurred and its device biodegrades, no movement of the pieces of the healed bone is possible. Claims 53 and 56 recite similar features to those in claims 7-10, discussed above.

New Claims

New claim 63-65 are being offered in this response, to more fully define subject matter for which protection is sought. Claim 63 is supported at least by the descriptions of materials in paragraphs 0031-0040 and Figures 1, 3, 5, and 7-8. The Casey reference does not disclose that its “reinforcement fiber” is not an ingredient of the material of its device 1. Claims 64 and 65 are

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supported at least by paragraphs 0033, 0045, and 0047-0048 and Figures 1, 3, 5, and 7-8. The Casey reference does not disclose placement of a reinforcing component on exterior surface(s) of an elongate member.

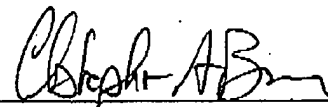
Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken in the Office Action that are not specifically addressed herein. Further, no limitation of the claims is intended by any of the remarks herein. The claims are intended to have the full scope to which their language entitles them, including equivalents.

Reconsideration and allowance of the pending claims in light of these remarks is respectfully requested. The undersigned attorney would welcome a call from Examiner Swiger to discuss any issues that may remain.

Respectfully submitted,

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